

## **REMARKS**

### **Rejections under 35 U.S.C. §112**

The Office Action rejects claims 11-25 under 35 U.S.C. §112 as failing to comply with the enablement requirement with respect to the claimed composition preventing hair loss. To advance prosecution, "preventing hair loss" was removed from the claims, which renders the rejection moot.

### **Rejections under 35 U.S.C. §102**

The Office Action rejects claims 11-16, 18, 20-22, and 24 under 35 U.S.C. §102(b) as anticipated by Korean patent 2001-0003366 (Bak *et al.*), US patent 6,027,728 (Yuen), JP patent 3-61-212513 (Ishida *et al.*), KR patent 2002-025152 (Ahn *et al.*), and JP patent 2000-119156 (Asano *et al.*). Applicants respectfully traverse.

Bak *et al.* use Asarum sieboldii (Asiasari radix) to increase blood circulation rather than to achieve the presently claimed synergistic effect of Asiasari radix extract, 5 $\alpha$ -reductase inhibitor, and activator of hair follicle cells to induce anagen phase of hair growth cycle by shortening the period taken in transfer from telogen phase to anagen phase of hair growth cycle, thereby rapidly regenerating hair. Bak *et al.* fail to teach or suggest the use of 5 $\alpha$ -reductase inhibitor and activator of hair follicle cells to achieve hair growth.

The Office Action states that Yuen teaches applying Sophora flavescens and Asarum Chinese wild ginger to the skin (page 5). However, according to North Carolina State University's College of Agriculture and Life Sciences ([www.ces.ncsu.edu/depts/hort/consumer/factsheets/groundcover/asarum\\_splendens](http://www.ces.ncsu.edu/depts/hort/consumer/factsheets/groundcover/asarum_splendens)), Asiasari radix (used in the present application) is not the same as Asarum Chinese wild ginger (used in the Yuen patent), the scientific name for which is Asarum splendens. Yuen does not teach using an activator of hair follicle cells such as hinokitiol and

nicotinamide. Further, Yuen's patent is directed to treating "eczema, psoriasis, allergic reactions, inflammatory rash" and applying this product "is intended to cause a temporary inflammation which removes at least an upper skin layer, with some mild to noticeable discomfort...". The present invention, however, is aimed at causing hair regeneration by inducing anagen phase of hair growth cycle as opposed to skin conditions. Yuen's product, which is directed at treating medical conditions exemplified by flaking of the skin, does not teach or suggest using the product for promoting hair growth.

Ishida *et al.* patent is directed to "provide the titled [pressure-sensitive adhesive] depilator having analgesic effect to suppress pain caused by the peeling of the depilation plaster from the skin". Ishida *et al.* do not teach using Asiasari radix to induce hair growth. One skilled in the art would not look to a patent discussing analgesics for skin peeling to induce hair growth. Further, Ishida *et al.* do not teach or use 5 $\alpha$ -reductase inhibitor and activator of hair follicle cells.

Ahn *et al.* claim a mixture used for treating dandruff by inhibiting the growth of two microorganisms. However, the present application is directed to a different invention (namely, inducing hair growth), and does not inhibit the growth of any microorganism as claimed by Ahn *et al.* nor does it treat dandruff. One skilled in the art would not look to literature describing compounds having antibacterial activity to induce hair growth. Further, Ahn *et al.* do not teach the synergistic effect of Asiasari radix extract, 5 $\alpha$ -reductase inhibitor, and activator of hair follicle cells to induce anagen phase of hair growth cycle.

Asano *et al.* neither teach nor suggest that their topical composition consisting of skin whitening agents, plant extracts, anti-inflammatory agents, and antioxidants would induce hair growth as disclosed and claimed in the present application. Asano *et al.* also do not teach the synergistic effect of Asiasari radix extract, 5 $\alpha$ -reductase inhibitor, and activator of hair follicle cells to induce anagen phase of hair growth cycle as claimed in the present application. Although the Office Action states that Asiasarum sieboldii (Asiasari radix) is used by Asano *et al.*, it is not mentioned as being part of their composition. Further, there is no reason to expect that, by using Sophora flavescens, Asano *et al.* would make a composition that would be effective in promoting hair growth.

Lastly, Asano *et al.* use cypress; this patent does not indicate that cypress was used for hinokitiol and cypress does have many other components.

### **Rejections under 35 U.S.C. §103**

The Office Action rejects claims 11-25 under 35 U.S.C. §103(a) as obvious over US patent 6,497,889 (Takekoshi *et al.*) in view of KR 10-2000-0038214 (Kim) and JP 61212513 (Ishida *et al.*). Applicants respectfully traverse.

As detailed in the claims and the specification, the present invention comprises active ingredients Asiasari radix extract, 5 $\alpha$ -reductase inhibitor (selected from at least one of Sophorae radix, Coicis semen, and Caryophylli flos extracts), and an activator of hair follicle cells (selected from at least one of hinokitiol and nicotinamide). Via research disclosed in the examples of the present application, the inventors found that a combination of Asiasari radix extract, 5 $\alpha$ -reductase inhibitor, and activator of hair follicle cells exhibits hair growth promoting effects without side effects, making the composition inventive over prior art. Further, Asiasari radix extract exhibits hair growth through a definite and previously unknown mechanism of induction via anagen phase of the hair growth cycle. Additionally, mixing the afore-mentioned active ingredients needs to happen in specific concentrations via a prescribed formula as claimed to achieve optimal hair growth (e.g., using a 10% Asiasari radix solution exhibited 72.4% hair growth area ratio compared with 98.9% area ratio upon synergistic use of 0.5% Asiasari radix, Sophorae radix, and hinokitiol; see tables 1, 3, 7, and 9).

The Office Action acknowledges that the Takekoshi *et al.* patent does not teach use of Asiasari radix, 5 $\alpha$ -reductase inhibitor, and hair follicle cell activator in one composition, but only that the reference teaches that each ingredient is suitable for combination in a pharmaceutical combination. The applicants respectfully traverse since Takekoshi *et al.* does not suggest, imply, or claim any experimental data for the successful combination of Asiasari radix, 5 $\alpha$ -reductase inhibitor, and hair follicle cell activator to have a synergistic effect of promoting hair growth. Takekoshi *et al.* offers no

specific formulation for hair growth so there is no teaching to combine the various combinations of plant extracts (Takekoshi *et al.*, column 7, lines 36-67 and column 8, lines 1-21) with disinfectants (column 7, lines 27-32) at all, much less to produce a hair growth product. Further, the mechanism by which the combination of Asiasari radix, 5 $\alpha$ -reductase inhibitor, and hair follicle cell activator promote hair growth is not taught; specifically, Takekoshi *et al.* uses hinokitiol as a disinfectant (Takekoshi *et al.*, column 7, line 27) and not a hair follicle activator, there is no mention of using *Sophora flavescens* as an 5 $\alpha$ -reductase inhibitor, and there is no mention of using *Asarum sieboldii* (Asiasari radix) to induce anagen phase of the hair growth cycle.

Takekoshi *et al.* patent does not teach, disclose, or suggest promoting hair growth, specifically using the three active ingredients presently claimed. Thus, one would not be driven to combine Asiasari radix of Takekoshi *et al.* with capsicum tincture and hinokitiol of Kim to provide a formulation for promoting hair growth or for any other reason. Further, Kim does not suggest or use Asiasari radix.

On page 11, the Office Action states that since skin is attached to hair, the use of Asiasarum sieboldi (Asiasari radix) on skin by Ishida *et al.* is combinable with Kim where various ingredients/extracts are added to hair. One skilled in the art would recognize that the permissibility (e.g., lack of toxicity) of using a compound on the skin and on the hair neither suggest making the combinations nor imply that the mixture of compounds if combined would be beneficial for promoting regrowth of hair by an unexpected mechanism. Further, Ishida *et al.* used a mixture containing Asiasarum sieboldi to provide an analgesic effect when applied topically and not, as presently claimed unexpected synergy of Asiasari radix with Sophorae radix and hinokitiol to promote hair growth. Additionally, Ishida *et al.* fail to teach or suggest the use of 5 $\alpha$ -reductase inhibitor and activator of hair follicle cells to achieve hair growth.

**CONCLUSIONS**

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance for pending claims 11, 18, 20-21, and 26-29 and that the application be passed to issue. Applicants respectfully request that a Notice of Allowance of the pending claims be timely issued in this case.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided. The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Respectfully submitted,

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/Keith G. Haddaway/  
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